

## **DETAILED ACTION**

### ***Acknowledgement of Applicant's Amendments***

1. The amendment made in claim 10 in the Amendment filed February 1, 2010 has been received and considered by Examiner.

### ***WITHDRAWN REJECTION***

2. The 35 U.S.C. 112, second paragraph, rejection of claim 10 made of record in the previous Office Action has been withdrawn due to Applicant's amendment in claim 10.

### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berghahn (USPN 3,757,979) in view of Sudo et al. (USPN 5,853,833).

Berghahn teach a safety closure-bottle assembly for medicine that comprises a capsule (bottle 5 of Berghahn) and a cap (safety closure 3 of Berghahn) (see, for example, Figures and col. 1, lines 3-8). Berghahn teach that the cap is formed of low density polyethylene (col. 6, lines 20-30). The recitation "for holding a dental implant with a fluid material preserving the dental implant" is an intended use phrase that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987). There is no indication in

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Berghahn that the bottle is anything other than a monolayer bottle (see, for example, Fig. 8).

Even if the bottle of Berghahn were a multilayer bottle (there is no indication of this in Berghahn), a single layer of this hypothetical multilayer bottle would correspond to the recited “capsule” (note that the “capsule” is recited as a component of the “package”).

Berghahn fails to teach that the capsule consists of cyclic olefin copolymer with an impermeability to moisture of less than 5% fluid loss per year. Berghahn fails to teach that the capsule consists of cyclic olefin copolymer because Berghahn does not specifically teach cyclic olefin copolymer.

Sudo et al. (USPN 5,853,833), however, disclose a sanitary container for medicine (see, for example, col. 6, lines 32-34 and col. 1, lines 5-15) having a polymeric layer that consists of cyclic olefin copolymer (see, for example, col. 3, lines 40-49), and that the cyclic olefin copolymer enables the contents of the container to be stably and sanitarily stored (col. 1, lines 5-15 and col. 2, lines 51-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used cyclic olefin copolymer as the material of the bottle 5 of Berghahn since cyclic olefin copolymer is known to be a polymeric material for containers of medical products that enables the contents of the container to be stably and sanitarily stored as taught by Sudo et al.

In regard to the recitation that the cyclic olefin copolymer has an impermeability to moisture of less than 5% fluid loss per year, the container taught by Berghahn and Sudo et al. meets the limitation regarding the maximum fluid loss per year because Berghahn and Sudo et al. teach all of the claimed structural and compositional limitations. Note also that Applicant's specification discloses that the “fluid loss per year” of cyclic olefin copolymer is “less than 5%”;

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and that this statement is not limited to any particular cyclic olefin copolymer of Applicant's invention, but rather is made generally in regard to cyclic olefin copolymer (which Applicant's specification describes as having "an excellent impermeability to moisture": cyclic olefin copolymer has "an excellent impermeability to moisture", Applicant's specification does not disclose any particular aspect of Applicant's invention that results in cyclic olefin copolymer having the recited "fluid loss per year"). See paragraph 0020 of Applicant's specification (page 4, lines 16-22).

In regard to claim 11, Berghahn and Sudo et al. teach the package as discussed above in regard to claim 10.

Berghahn fails to explicitly teach that the package includes a barrier sealing the capsule.

Sudo et al. (USPN 5,853,833), however, disclose that the sanitary container may include a silicon oxide coating applied to the surface of the cyclic olefin container (see, for example, col. 9, lines 10-17) that improves the transmission resistance to oxygen and nitrogen of the cyclic olefin container (see, for example, col. 3, lines 5-19). This silicon oxide coating corresponds to the barrier sealing the capsule claimed in claim 11.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the capsule of the package taught by Berghahn and Sudo et al. with the silicon oxide coating of Sudo et al. in order to improve the transmission resistance to oxygen and nitrogen of the cyclic olefin container of Sudo as taught by Sudo et al.

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5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berghahn (USPN 3,757,979) in view of Sudo et al. (USPN 5,853,833) and in further view of Sudo (USPN 5,723,189).

Berghahn and Sudo et al. teach the package as discussed above in regard to claim 10.

Berghahn and Sudo et al. fail to explicitly teach an ampoule within the capsule, where the ampoule is formed of cyclic olefin copolymer.

Sudo (USPN 5,723,189), however, discloses that it is well known in the art that ampoules containing liquid medicament are enclosed in a container (col. 1, lines 64-66) in order to maintain the sanitary nature of the medicament during storage of the medicament in a container (col. 1, lines 9-17) and that the cyclic olefin copolymer is suitable for use as any of a multiplicity of containers such as cases, sacks, vials, press through packs, slip pouches, partitioned vessels, ampoules “and the like) (col. 12, lines 28-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have stored ampoules in the capsule taught by Berghahn and Sudo et al. since it is well known in the art that ampoules containing liquid medicament are enclosed in a container in order to maintain the sanitary nature of the medicament during storage of the medicament in a container as taught by Sudo, and to have used cyclic olefin copolymer as the material of the ampoules since cyclic olefin copolymer is a suitable material for use as the material of ampoule used to store medicament as taught by Sudo et al. ‘833 (and as also taught by Sudo ‘189).

***Response to Arguments***

6. Applicant's arguments presented in the Amendment filed February 1, 2010 in regard to the 35 U.S.C. 103 rejection of claims 10 and 11 over Berghahn (USPN 3,757,979) in view of Sudo et al. (USPN 5,853,833) have been fully considered but are not persuasive.

Berghahn (USPN 3,757,979) and Sudo et al. (USPN 5,853,833) teach the claimed article for the reasons of record in the updated rejection made of record in this Office Action. Both containers of Berghahn and Sudo et al. are containers for storing medicine, and therefore are analogous (and therefore combinable) references. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used cyclic olefin copolymer as the material of the bottle 5 of Berghahn since cyclic olefin copolymer is known to be a polymeric material for containers of medical products that enables the contents of the container to be stably and sanitarily stored as taught by Sudo et al.

Applicant appears to argue in the paragraph bridging pages 3 and 4 of the Amendment that Berghahn requires that the container hold only solid materials, but the goal of Berghahn to protect children from "dangerous materials" (col. 1, line 20) makes the container of Berghahn applicable to materials other than solid materials. There are "dangerous materials" that are not solid.

Applicant argues that the proposed combination of references does not teach a capsule that consists of cyclic olefin copolymer because the secondary reference Sudo requires an inorganic coating along with the cyclic olefin copolymer layer. However, the primary reference Berghahn does not require an inorganic layer, and Sudo is relied upon for its teaching of cyclic olefin copolymer layer as a suitable polymeric material for a container for the stable and sanitary

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storage of medicine. The rejection of record proposes to modify the container of Berghahn based on the teachings of Sudo, not to modify the container of Sudo. Sudo uses the inorganic layer to increase the gas impermeability of the container, but Berghahn does not discuss gas impermeability. Applicant's claimed subject matter also does not pertain to gas impermeability: moisture is not a gas.

In regard to the recitation that the cyclic olefin copolymer has an impermeability to moisture of less than 5% fluid loss per year, the container taught by Berghahn and Sudo et al. meets the limitation regarding the maximum fluid loss per year because Berghahn and Sudo et al. teach all of the claimed structural and compositional limitations. Note also that Applicant's specification discloses that the "fluid loss per year" of cyclic olefin copolymer is "less than 5%"; and that this statement is not limited to any particular cyclic olefin copolymer of Applicant's invention, but rather is made generally in regard to cyclic olefin copolymer (which Applicant's specification describes as having "an excellent impermeability to moisture": cyclic olefin copolymer has "an excellent impermeability to moisture", Applicant's specification does not disclose any particular aspect of Applicant's invention that results in cyclic olefin copolymer having the recited "fluid loss per year"). See paragraph 0020 of Applicant's specification (page 4, lines 16-22).

In the sentence bridging pages 5 and 6 of the Amendment, Applicant appears to argue that the bottle of Berghahn is not formed exclusively of a certain material. However, since Berghahn requires nothing other than a polymeric material as the material of the bottle (col. 5, lines 5-15), the bottle of Berghahn consists of the polymeric material.

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In the first full sentence on page 6 of the Amendment, Applicant states “the Examiner fails to recognize the difference between an article made of a single material and an article constructed out of a single layer”. However, it is unclear how this is the case. Since Berghahn requires nothing other than a polymeric material as the material of the bottle (col. 5, lines 5-15), the bottle of Berghahn consists of the polymeric material. Applicant appears to allege that there is something other than the polymeric material in the bottle of Berghahn, without providing any support for this allegation. Clarification is requested. The arguments of counsel cannot take the place of evidence in the record. MPEP 716.01(c)II. Berghahn does not require anything other than the polymeric material.

7. Applicant’s arguments presented in the Amendment filed February 1, 2010 in regard to the 35 U.S.C. 103 rejection of claim 18 over Berghahn (USPN 3,757,979) in view of Sudo et al. (USPN 5,853,833) and in further view of Sudo (USPN 5,723,189) have been fully considered but are not persuasive. Applicant’s arguments depend upon Applicant’s arguments in regard to the 35 U.S.C. 103 rejection of claims 10 and 11 over Berghahn (USPN 3,757,979) in view of Sudo et al. (USPN 5,853,833), which have been addressed above.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 7:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye, can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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